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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/344,226	06/25/1999	RONALD H. CHIARELLO	2574.008US0	8804

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT

PAPER NUMBER

1626
DATE MAILED: 04/08/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/344,226	CHIARELLO ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,5-8 and 10-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 5-8, 10-23 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____.

Claims 1, 5-8, 10-23 are pending in this application.

Claims 2-4, 9, are canceled.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.117(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/24/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-8, 21-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to disclose how one of ordinary skill in the art would determine "a determinable wavelength." Therefore, the specification fails to provide adequate support for claims 1, 5-8, 21-23. By adding how the wavelength could be determined to the specification the rejection would be overcome. However, applicants should note that the introduction of new subject matter into the specification would raise the issue of new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 5-8, 21-23, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 23 are written in functional language and therefore, broader than the enabling disclosure. For example, the claims recite "conjugating the fluorophore with a " line 12, page 3, "determinable wavelength" on the last line; and claim 5 recites "attached to a solid support" line 1. Therefore, claims 1, 5-8, 21-23, are indefinite. The claims must recite how one of ordinary skill in the art would perform the conjugation (attachment) and determine the wavelength. The claims must recite all the relevant conditions involve in the process.

Claim 1 is an omnibus type claim. For example, as written, there is no relationship between "an organic compound" on line 1, and the rest of the claim. The claim recites "conjugating the fluorophore with a biomolecule" and characterized the resultant conjugate. The claim fails to state how the conjugate is applicable in "labeling an organic compound."

A claim must stand alone to define the inventions, and incorporation into the claims by reference to the specification or an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608, BdPatApp & Inter. (1993). Applicant may not claim all processes of making conjugates of the instant compounds, known and yet to be developed. Applicant must claim only the process that embodies applicant's invention.

Under US patent practice a process claim must recite at least one positive step. See the MPEP. The positive step must set forth the "how to" not "what." The instantly claimed process does not recite a single positive step.

Applicants' arguments filed 3/24/03 have been fully considered but they are not persuasive. Applicant argues that the ruling in *Ex parte Fressola*, is not applicable in the instant because the claims do not refer to the specification but, at the same time applicant states the claims are not indefinite and refers the Examiner to the specification. This is not persuasive because of the contradictory nature of the argument. Applicant also contends that one of ordinary skill in the art would understand the scope of the claims in light of the specification. This is not persuasive for reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al., US 4,647,675, in view of Arnost et al., US 4,900,686, alone and/or Kang US 5,846,737.

Applicants claim conjugated rhodamine dyes of generic formula 1, having several substituents. For example, R1 to R14 are each H; R2-R9 are each alkyl; Ra is alkyl, cycloalkyl or aryl and Z is a linker and the conjugated substance. Also, R1-R2, R5-R6, and R9 to R14 are each halogen.

Determination of the scope and content of the prior art (MPEP §2141.01)

Mayer et al., teach the same rhodamine dyes having formula 1, with several substituents. For example, R, R1 to R3 are each H; R4 and R5 are each alkyl, cycloalkyl; one of R4 and R5 is H or aryl; X and Y are each H or chlorine. See the abstract, specific species in columns 1-7, and claims 1-5.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Mayer et al., is that in the instant invention the rhodamine dyes are being claimed as conjugate while Mayer et al., do not teach the conjugates.

Finding of prima facie obviousness--rational and motivation (MPEP §2142.2413)

Arnott et al., teach rhodamine dyes are commonly used as conjugates in biological diagnostic assays, and that the most commonly used dyes are fluorescent dyes (column 1, lines 1-40). Kang teaches rhodamine dyes, and their method of use as conjugate of peptides, proteins nucleotides, etc. (column 1, lines 1-4). Kang also, teaches the conjugation of rhodamine dyes to bacteria, virus, yeast, and to immobilized solid or semi-solid support, such as polymer, membrane, polymeric particle, (microsphere), etc. See column 10, lines 10-18. Therefore, the instant invention is prima facie obvious from the teachings of Mayer et al., Arnott et al., and Kang. One of ordinary skill in the art would have known to conjugate the rhodamine dyes of Mayer et al., at the time the instant invention was made. The motivation for making the conjugates is because it is well known in the art that rhodamine dyes are used in making fluorescent conjugates. For example, see the prior arts of Arnott et al., and Kang.

Applicants' arguments filed 3/24/03 have been fully considered but they are not persuasive. Applicant argues that the prior art of Mayer et al., is nonanalogous art, because Meyer et al., discloses a different utility. This is not persuasive because the rejection is based on the fact that compounds of Meyer et al., are rhodamines. The selection of a known compound based on its suitability for its intended use is prima facie obvious, *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Applicant also argues that the rhodamine compounds of Kang conjugates have sulfur substituents. This is not persuasive

because the instant rejection is not anticipatory. Applicant contends that the Examiner having knowledge of relevant fact must submit an affidavit in support of the statement that rhodamine dyes are well known in the art for making fluorescent conjugates. This is not persuasive because the Examiner has relied only on facts of prior arts, and the Examiner could not be obliged to produce documentary proof if the knowledge is of notorious character, *In re Malcolm*, 129 F.2d 529 (CCPA 1942). In the instant application, rhodamine dyes are well known in the art for making fluorescent conjugates. For example, see the prior arts of Arnost et al., and Kang.

The problem with applicant's position starts with applicant arguing against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Hence, the totality of applicant's contention is directed toward anticipatory rejection.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Taofiq A. Solola whose telephone number is (703) 308-4690. The Examiner is on flexible work schedule and the best days to get him are Mondays, Wednesdays and Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



TADFIQ SOLOLA
PRIMARY EXAMINER

Group 1626

April 5, 2003